IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants	:	Paul T. GARDINER et al.
Serial No.	:	10/799,038
Filed	:	March 11, 2004
For	:	Food Supplement for Increasing Lean Muscle Mass and Strength
Examiner	:	Frank Choi
Art Unit	:	1616

Mail Stop Amendment
Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

DECLARATION OF DR. MARVIN A. HEUER UNDER 37 C.F.R. §1.132

Sir:

I, Dr. Marvin A. Heuer, do hereby declare the following:

1) I am one of ordinary skill in the art with respect to the field of medicine, and particularly in the fields of nutrition and nutritional supplementation. A copy of my Curriculum Vitae, evidencing my experience in these fields, is attached herewith.

2) I have read and understand the present application including the claims as originally filed.

3) I have read and understand the Office Action dated December 13, 2006 ("Office Action") in connection with the present application.

4) New Claim 98 is directed to "a method for supplementing the diet of a human comprising orally administering a dietary supplement comprising effective amounts of protein and a compound which mimics or enhances insulin activity to

enhance muscle size and strength." Support for this claim is found in the Specification, which states at page 3, line 31 – page 4, line 23, that:

> "[t]he food supplements and methods of the present invention may provide further and significant size and strength enhancement through the role of certain substances which mimic and/or increase the sensitivity of insulin, in conjunction with a source of amino acid. . . , increased availability of these GPI precursors, increase insulin sensitive and these GPIs can trigger insulin signalling pathways and events independent of insulin thereby mimicing the effects of insulin . . . and can thereby increase the development of muscle cells. Consequently, **supplements which comprise a substance which can enhance and/or mimic insulin activity, and a source of amino acids, preferably any source of protein, more preferably, whey, may provide *further and significant muscle size and strength enhancement as compared with supplements employing only proteins or amino acids*.**" Emphasis added.

5) For the reasons set forth below, it is my opinion that supplements which comprise a substance which can enhance and/or mimic insulin activity, and a protein ***do***, in fact, provide further and significant muscle size and strength enhancement as compared with supplements employing only proteins or amino acids. This opinion is evidenced, for example, by:

> I. "The Effects of Whey Protein Supplementation and Resistance Training on Body Composition and Strength", Burke, D., et al. (2001), Int J Sport Nutr Exerc Metab 11:349 (an Abstract copy of which is attached herewith), which states that "[t]he results show that, when combined with a resistance-training program, NITRO-TECH supplementation produces greater increases in lean mass and 1RM bench press than pure whey protein or a placebo." NITRO-TECH, a product label being attached herewith, is an example of a

supplement which comprises a substance which can enhance and/or mimic insulin activity and a protein, as claimed.

II. Before/After photographs (copies of which are attached herewith) of subjects that ingested NITRO-TECH (details of consumption provided on an individual basis), demonstrating that the administration of supplements which, like NITRO-TECH, comprise a substance which can enhance and/or mimic insulin activity, and a protein ***do***, in fact, provide further and significant muscle size and strength enhancement as compared with supplements employing only proteins or amino acids.

The undersigned declares that all statements made herein of his own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the life so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States code and this such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Date: June 11, 2007

Dr. Marvin A. Heuer

MuscleTech-Funded

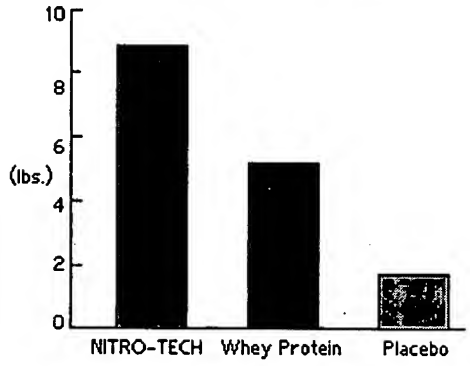
——— RESEARCH ABSTRACT———

The Effects of Whey Protein Supplementation and Resistance Training on Body Composition and Strength.

Burke, D., et al. (2001). *Int J Sport Nutr Exerc Metab.* 11:349.

In order to stay in positive nitrogen balance, resistance-training persons need to consume more than the recommended daily intake of protein. This study was designed to assess the effects of NITRO-TECH® supplementation (1.2 grams per kilogram of bodyweight per day), or an equal dose of pure whey protein, or a placebo over the course of a 6-week resistance-training program. Thirty-six trained males were randomly assigned to one of the 3 groups and were tested for changes in muscular strength (1 RM bench press, 1 RM squat, and isokinetic leg extension power) and body composition. Subjects using NITRO-TECH had significantly greater gains in lean mass (over 8 lbs. vs. over 5 lbs.), 1 RM bench press (over 30 lbs. vs. less than 14 lbs.), and isokinetic leg extension power in comparison with subjects that used whey protein. The results show that, when combined with a resistance-training program, NITRO-TECH supplementation produces greater increases in lean mass and 1 RM bench press than pure whey protein or a placebo. Therefore, the addition of novel ingredients can increase the effectiveness of whey protein supplementation.

Changes in Lean Mass

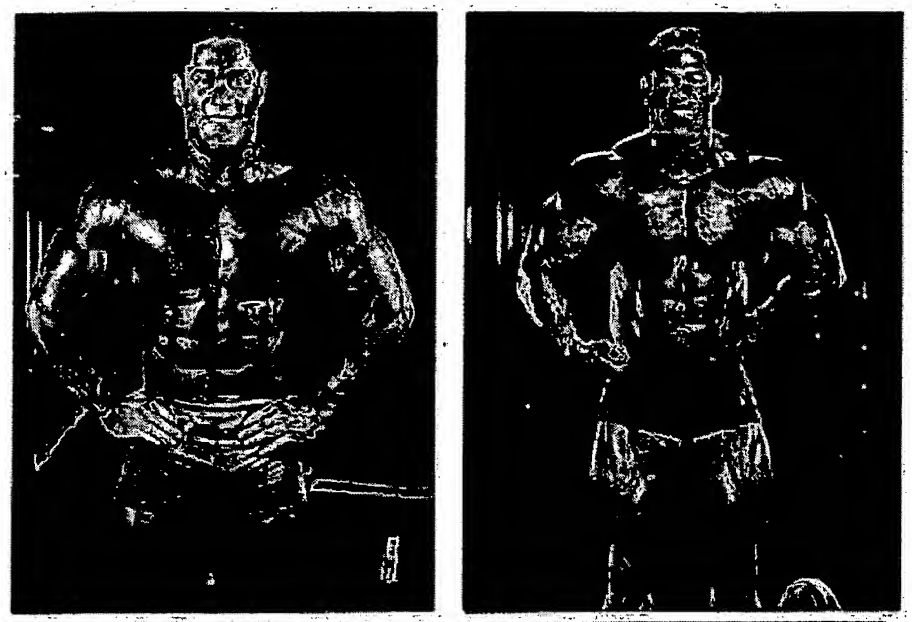


NITRO-TECH subjects gained an average of over 8 lbs. of lean mass.

Conclusion: In this 6-week study, NITRO-TECH® subjects gained an average of over 8 pounds of lean mass. Subjects using NITRO-TECH, increased their max bench press by an average of over 30 lbs. Subjects using regular whey protein gained an average of less than 14 lbs. on their max bench press.

Nitro-Tech Hardcore B&A's

BADELL, Gustavo



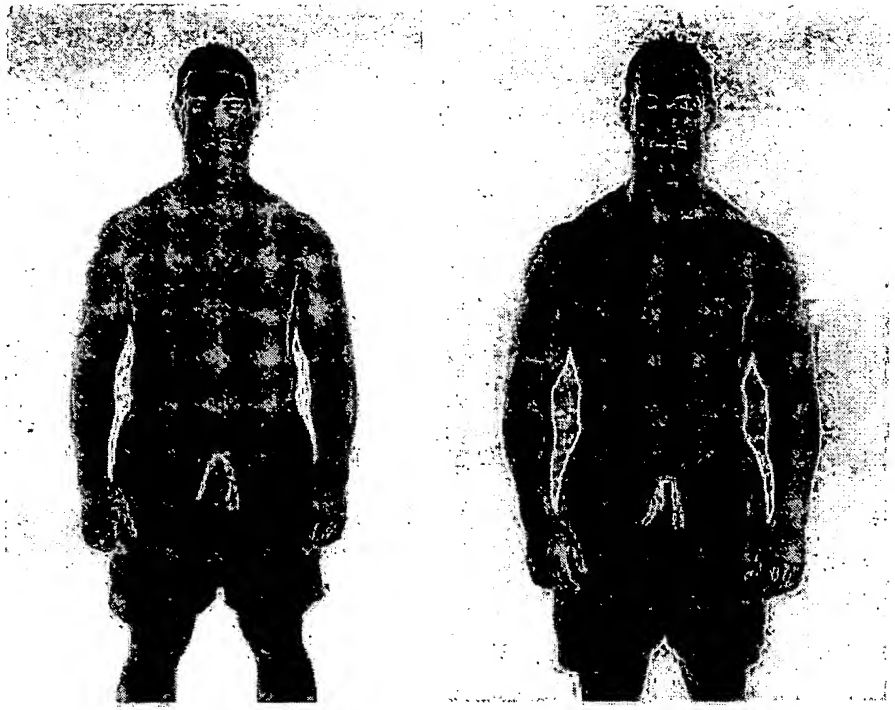
Contract Details – Expires Dec 31, 2008

Other Information –
- IFBB Pro Bodybuilder.
- 2 Career Pro Wins
- 2005 Olympia Challenge Round Champion

- Products Used
  - Muscletech
  - B&A – Nitro Tech Hardcore
- Date of Transformation
  - Start: 2002
  - Finish: 2003
- Stats
  - Weight – gained 24 pounds

Pro Career Top 6 Finishes
- 2006 Olympia Weekend
Men (Place: 6)
- 2006 San Francisco Pro
Men: Men (Place: 1)
- 2006 Arnold Classic
Men: Men (Place: 4)
- 2005 Olympia Weekend
Men: Men (Place: 3)
- 2005 Arnold Classic
Men (Place: 3)
- 2005 Ironman Pro Invitational
Men (Place: 1)
- 2004 Olympia Weekend
Men (Place: 3)
- 2004 Olympia Weekend
Men (Place: 3)
- 2004 GNC
Men (Place: 3)
- 2004 San Francisco Pro
Men (Place: 4)
- 2004 Ironman Pro Invitational
Men (Place: 3)
- 2002 Toronto Pro
Men (Place: 3)
- 2002 Southwest Pro
Men (Place: 6)

BAKER, Brad



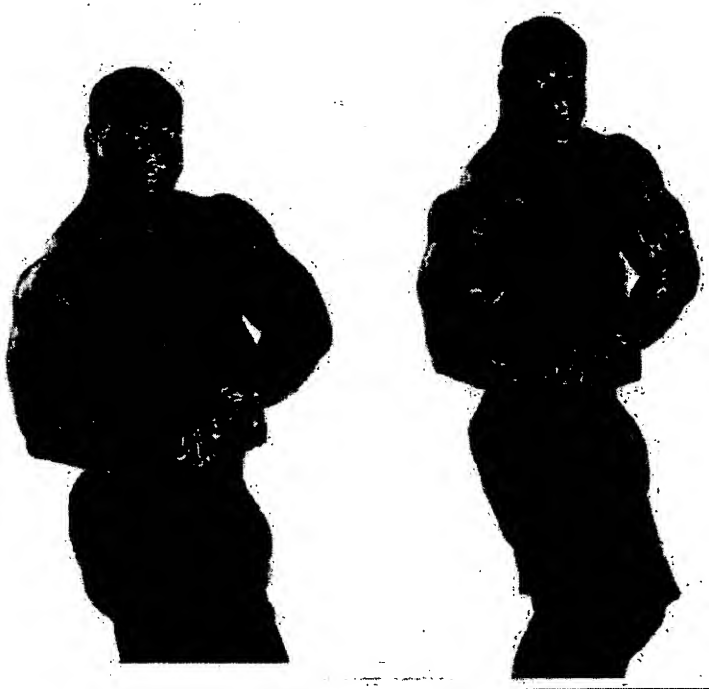
Contract Details – Not Perpetual Use
Contract Ends December 31, 2007

Other Information – Used as Fitness athlete.
- Used Nitro-Tech Hardcore with other MuscleTech supplements

- Products Used
  - Nitro-Tech Hardcore for 13 weeks and gained 15 pounds of muscle.

CORMIER Chris

- **Products Used**
  - **Nitro-Tech Hardcore for 12 Weeks**



Contract Details – Perpetual Use
Expires: Dec 31, 2007

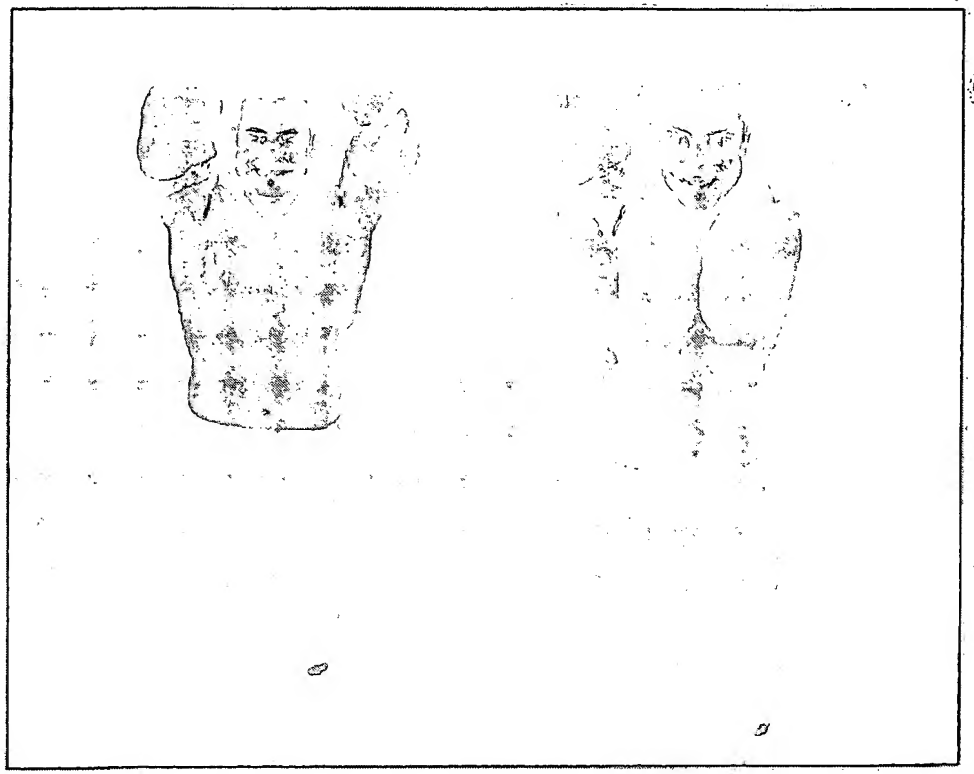
Other Information
- **IFBB pro Bodybuilder.**
- **11 Pro Wins**
- **Used NitroTech Hardcore with other MuscleTech supplements.**

•2005 Grand Prix Australia
•Men (Place: 2)
•2005 San Francisco Pro
•Men (Place: 1)
•2005 Arnold Classic
•Men (Place: 2)
•2004 British Grand Prix
•Men (Place: 2)
•2004 Grand Prix Holland
•Men (Place: 2)
•2004 Grand Prix Australia
•Men (Place: 2)
•2004 Arnold Classic
•Men (Place: 2)
•2003 Grand Prix Australia
•Men (Place: 1)
•2003 San Francisco Pro
•Men (Place: 2)
•2003 Arnold Classic
•Men (Place: 2)
•2002 GNC
•Men (Place: 3)
•2002 Grand Prix Holland
•Men (Place: 2)
•2002 British Grand Prix
•Men (Place: 3
•2002 Olympia Weekend
•Men (Place: 3)
•2002 Grand Prix Australia
•Men (Place: 1)
•2002 Austrian Pro
•Men (Place: 1)
•2002 San Francisco Pro
•Men (Place: 2)
•2002 Arnold Classic
•Men (Place: 2)

•2002 Ironman Pro Invitational
•Men (Place: 1)
•2001 Grand Prix New Zealand
•Men (Place: 2)
•2001 British Grand Prix
•Men (Place: 2)
•2001 Olympia Weekend
•Men (Place: 5)
•2001 Grand Prix Australia
•Men (Place: 1)
•2001 European Pro
•Men (Place: 2)
•2001 Arnold Classic
•Men (Place: 2)
•2001 San Francisco Pro
•Men (Place: 1)
•2001 Ironman Pro Invitational
•Men (Place: 1)
•2000 Arnold Classic
•Men (Place: 2)
•2000 Ironman Pro Invitational
•Men (Place: 1)
•1999 Olympia Weekend
•Men (Place: 3)
•1999 Arnold Classic
•Men (Place: 3)
•1999 Ironman Pro Invitational
•Men (Place: 1)
•1998 Grand Prix Finland
•Men (Place: 4)
•1998 Grand Prix Germany
•Men (Place: 4)
•1998 Olympia Weekend
•Men (Place: 6)
•1998 Arnold Classic
•Men (Place: 5)

•1997 Grand Prix Russia
•Men (Place: 4)
•1997 Grand Prix Finland
•Men (Place: 2)
•1997 Grand Prix Czech
•Men (Place: 2)
•1997 British Grand Prix
•Men (Place: 2)
•1997 Grand Prix Germany
•Men (Place: 6)
•1997 Grand Prix Spain
•Men (Place: 6)
•1997 IFBB Night of Champions
•Men (Place: 1)
•1997 Toronto Pro
•Men (Place: 3)
•1995 Grand Prix Ukraine
•Men (Place: 4)
•1995 Grand Prix France
•Men (Place: 5)
•1995 Grand Prix Russia
•Men (Place: 5)
•1995 British Grand Prix
•Men (Place: 5)
•1995 Grand Prix Germany
•Men (Place: 4)
•1995 Grand Prix Spain
•Men (Place: 4)
•1995 Olympia Weekend
•Men (Place: 6)
•1995 IFBB Night of Champions
•Men (Place: 4)
•1994 Olympia Weekend
•Men (Place: 6)
•1994 Arnold Classic
•Men (Place: 4)
•1994 Ironman Pro Invitational
•Men (Place: 2)

DAHDOUGH, Gabriel



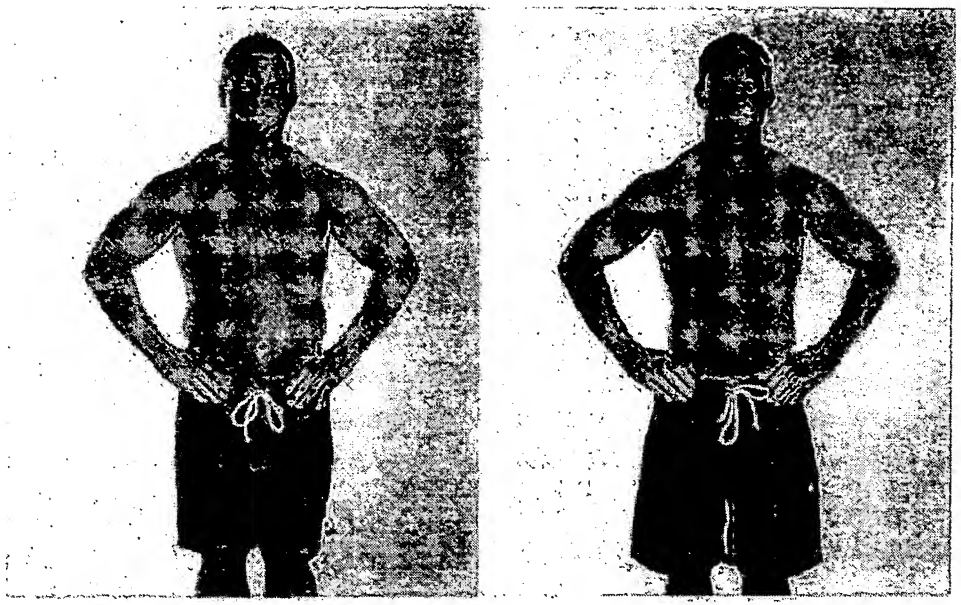
- Products Used
  - Nitro-Tech Hardcore for 15 weeks.

Contract Details – Perpetual Use

Other Information –

Used Nitro-Tech Hardcore with other MuscleTech supplements

HILLIER, Steve

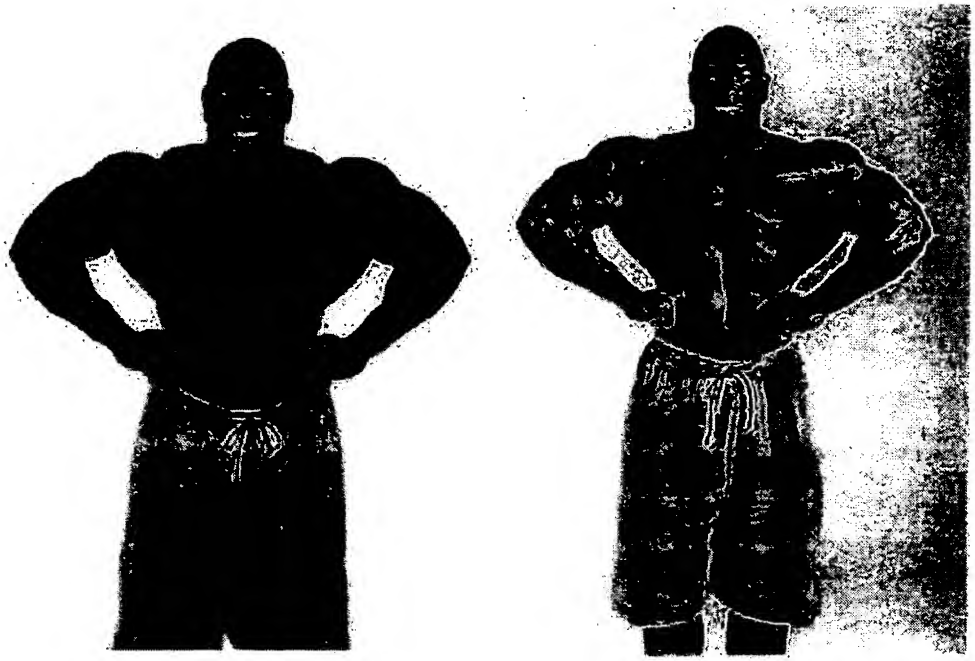


- Products Used
  - Nitro-Tech Hardcore for 18 Weeks.

Contract Details – Perpetual Use

Other Information –

JACKSON, Johnnie



- Products Used

- NitroTech Hardcore for 6 weeks.

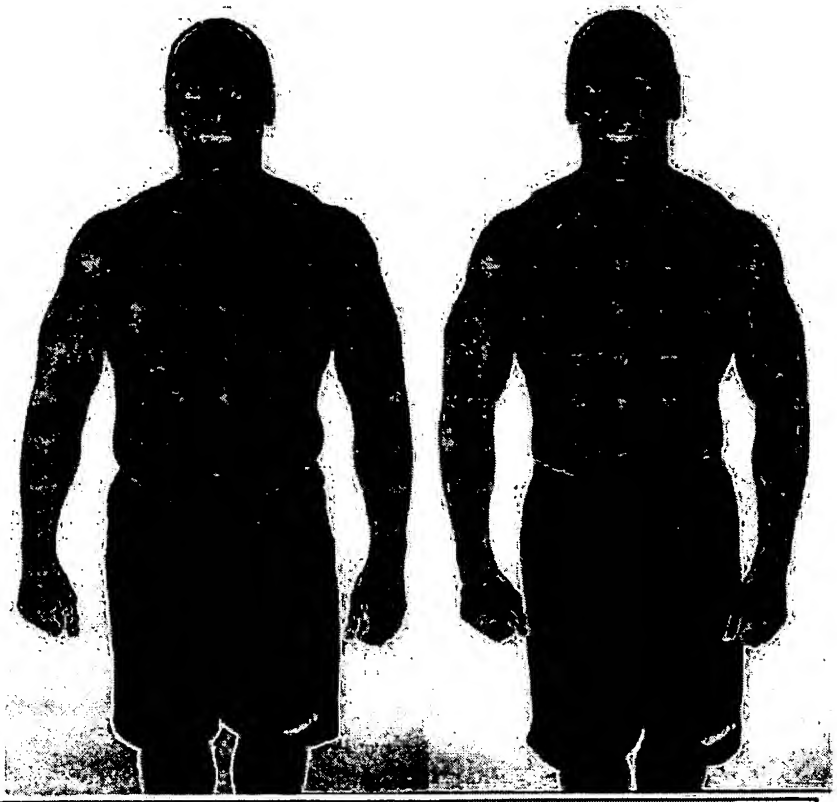
Pro Career Top 6 Finishes

- 2006 Atlantic City Pro
- Men (Place: 2)
- 2006 Grand Prix Montreal
- Men (Place: 1)
- 2006 Europa Super Show
- Men (Place: 3)
- 2005 Europa Super Show
- Men: Men (Place: 2)
- 2005 Toronto Pro
- Men (Place: 2)
- 2004 Toronto Pro
- Men (Place: 2)
- 2004 Grand Prix Hungary
- Men (Place: 5)
- 2003 Grand Prix Holland
- Men (Place: 5)
- 2003 British Grand Prix
- Men (Place: 5)
- 2003 IFBB Night of Champions
- Men (Place: 5)
- 2003 Night of Champions
- Men (Place: 5)

Contract Details – Not Perpetual Use
Dec 31, 2007

Other Information – Team MuscleTech athlete.
IFBB Pro Bodybuilder
- Used Nitro-Tech Hardcore with other MuscleTech Supplements.

MacWILLIAM, Cal

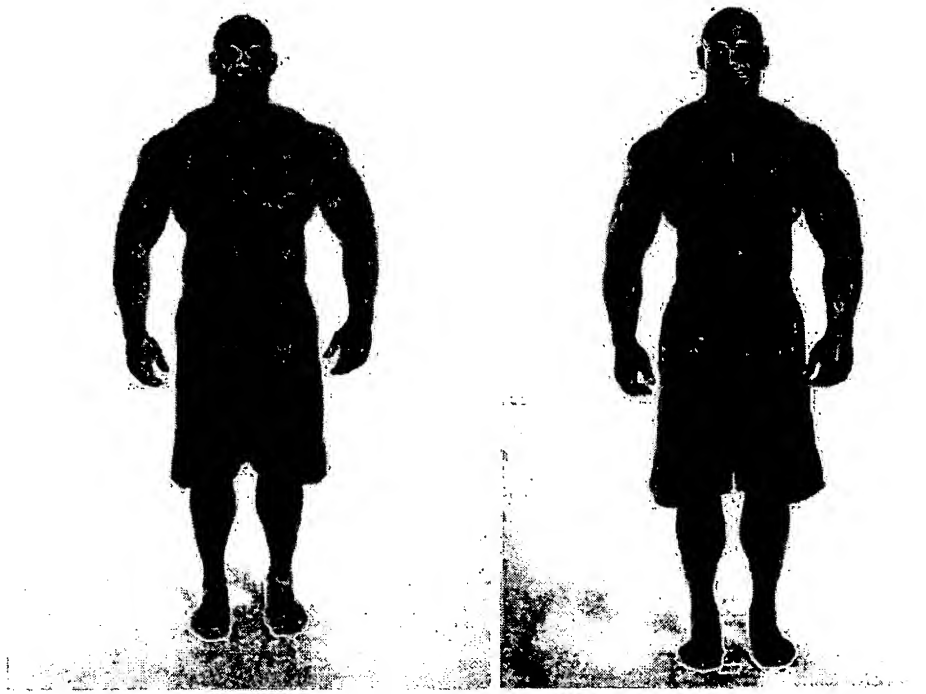


- Products Used
  - Nitro-Tech Hardcore for 13 weeks

Contract Details – Perpetual Use

Other Information –

POSJEPAL, Eric

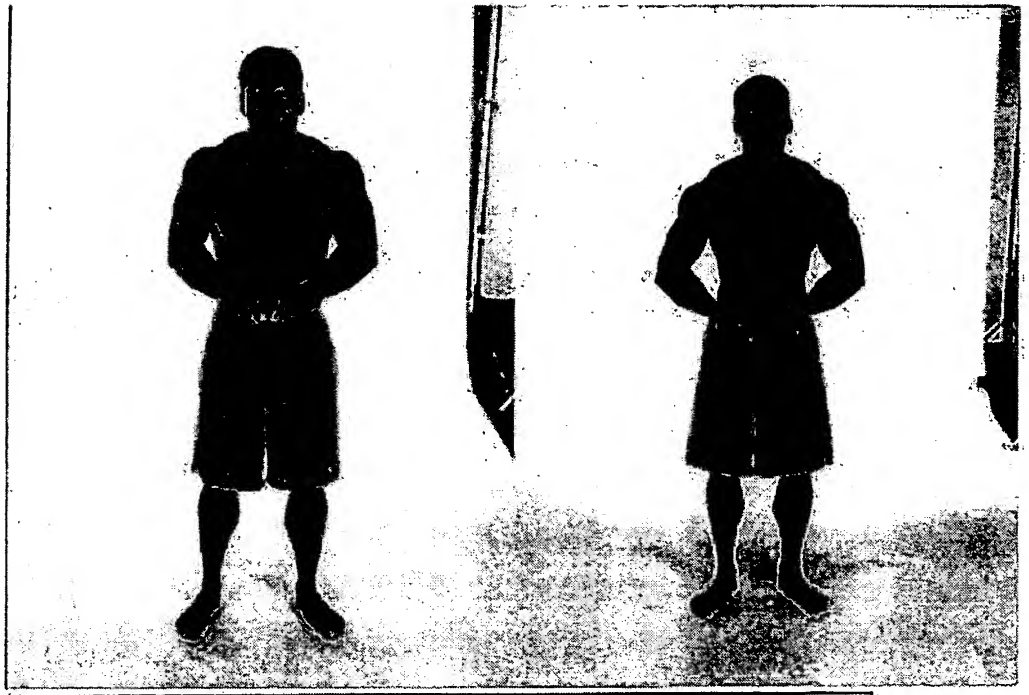


- **Products Used**
  - **Nitro-Tech Hardcore for 15 weeks**

Contract Details – Not Perpetual Use
Expires: May 1, 2007

Other Information –
Used Nitro-Tech Hardcore with other MuscleTech supplements

RUSKA, Reiner

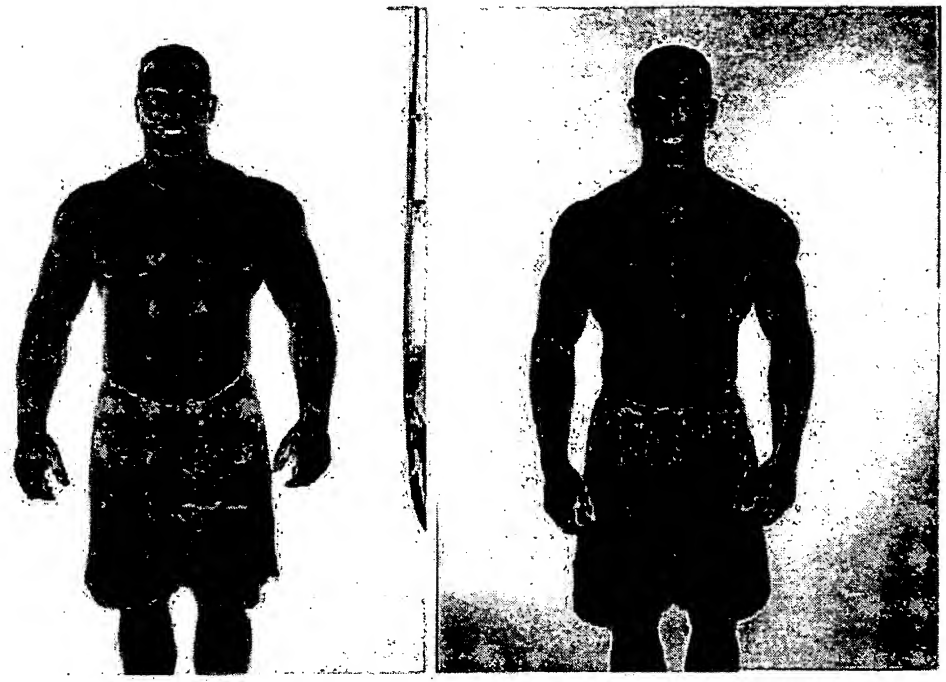


Contract Details – Perpetual Use

Other Information –

- Products Used
  - Nitro-Tech hardcore for 11 weeks

SACKET, Brad



- **Products Used**
  - **Nitro-Tech Hardcore for 17 weeks**

Contract Details – Perpetual Use

Other Information –

Used Nitro-Tech Hardcore with other MuscleTech supplements

SMITH, Sam

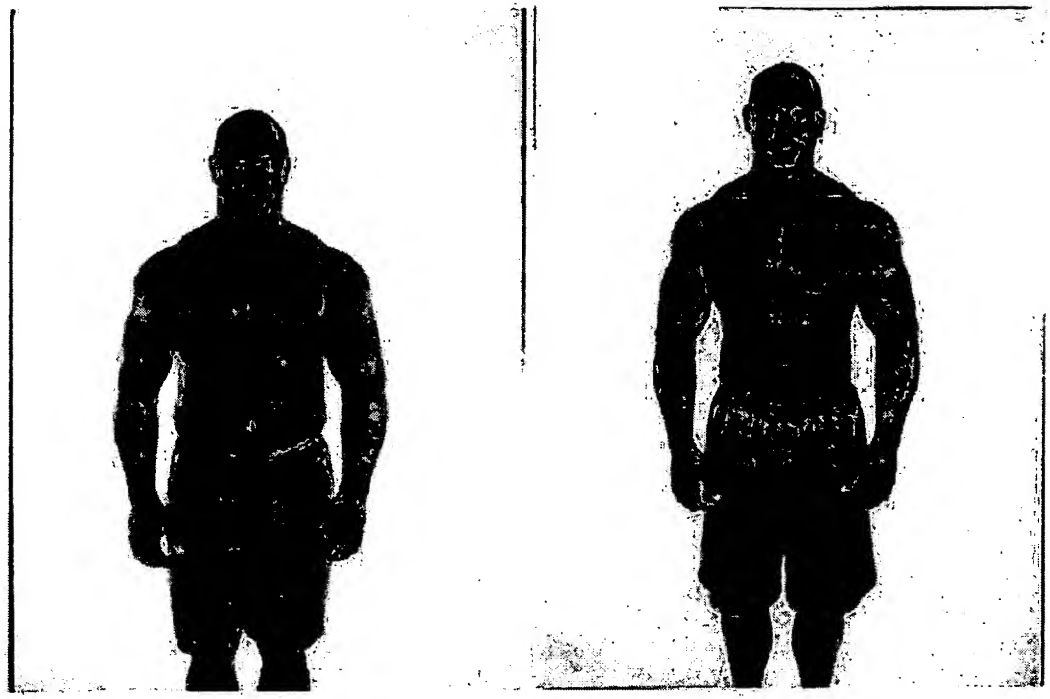
- Products Used
  - Nitro-Tech Hardcore for 16 weeks

Contract Details – Perpetual Use

Other Information –

Used Nitro-Tech Hardcore with other MuscleTech supplements

ST. PIERRE, Marc

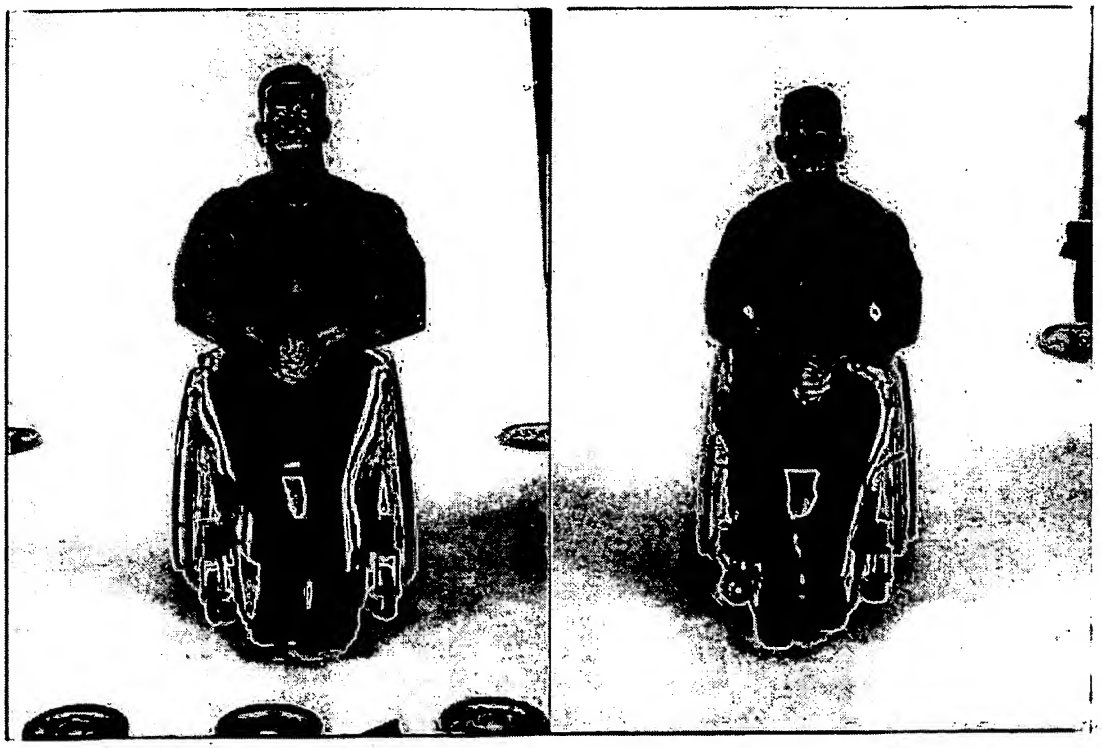


- Products Used
  - Nitro-Tech Hardcore for 16 weeks

Contract Details – Perpetual Use

Other Information –

TRENTI, Carlo



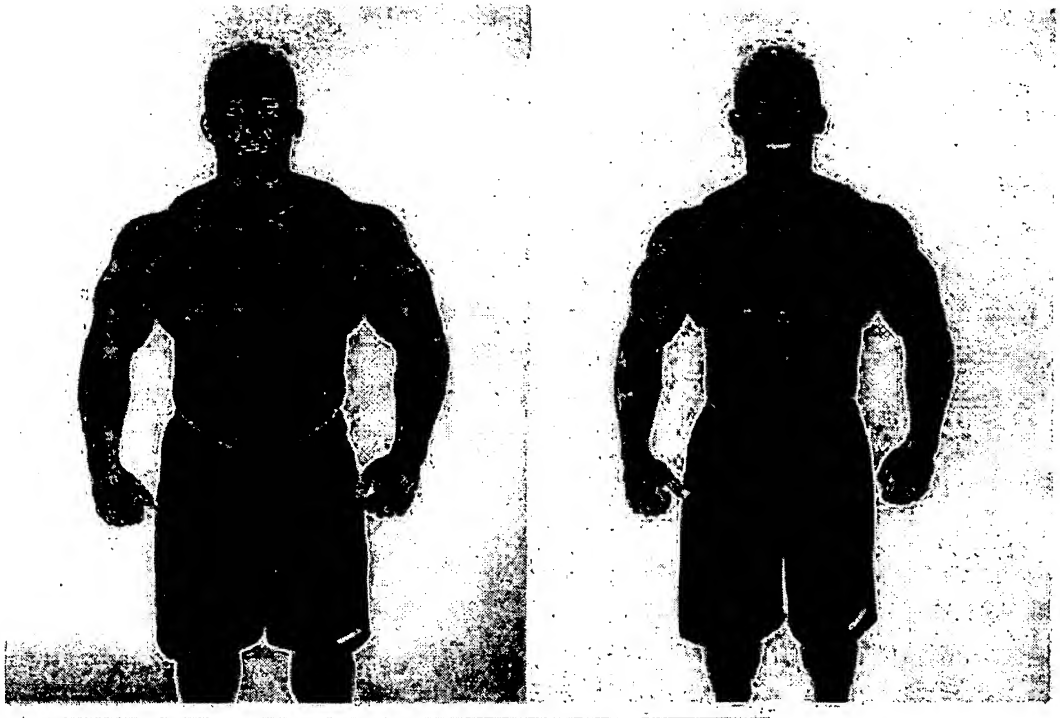
- Products Used
  - Nitro-Tech Hardcore for 17 weeks.

Contract Details – Perpetual Use

Other Information –

Used Nitro-Tech Hardcore with other MuscleTech supplements

ZONA, Sebastian



Contract Details – Not Perpetual Use
Expires: Aug 31, 2007

Other Information – Team MuscleTech athlete and amateur bodybuilder.
Used Nitro-Tech Hardcore with other MuscleTech supplements

- Products Used
  - Nitro-Tech Hardcore for 16 weeks.

Supplement Facts

Serving Size 1 Scoop (28.5 g)
Servings Per Container Approx. 63

Amount Per Serving	% Daily Value
Calories 110	
Calories from Fat 15	
Total Fat 1.5 g	2%*
Saturated Fat 1 g	6%*
Cholesterol 50 mg	17%*
Total Carbohydrate 3 g	1%*
Dietary Fiber 1 g	4%*
Sugars 2 g	†
Protein (featuring Nano-Diffuse™ Technology) 20 g	40%*
Vitamin A 25 IU	1%
Vitamin E (as as dl-alpha tocopheryl acetate) 30 IU	100%
Vitamin B6 (as pyridoxine hydrochloride) 10 mg	500%
Folic acid 400 mcg	100%
Calcium 130 mg	13%
Iron 0.2 mg	1%
Phosphorus (as dipotassium phosphate) 90 mg	9%
Magnesium (as magnesium oxide) 45 mg	11%
Sodium 60 mg	3%
Potassium (as dipotassium phosphate) 200 mg	6%
SynthePro® (Ultra-Absorbing Amino Acid Matrix) 2020 mg	†
Creatine monohydrate	†
Calcium alpha-ketoglutarate	†
L-methionine	†
L-phenylalanine	†
Phenylalanine methyl ester HCl	†
Glutamine alpha-ketoglutarate	†
Glutamine ethyl ester HCl	†
Glutamine methyl ester	†
L-histidine	†
L-threonine	†
L-valine	†
Valine ethyl ester	†
L-lysine monohydrochloride	†
L-leucine alpha-ketoglutarate	†
L-leucine pyroglutamate	†
Isoleucine ethyl ester HCl	†
L-isoleucine	†
Lactoferrin	†
Insulogen® (Anabolic Insulin Drivers) 921 mg	†
Cyamopsis tetragonoloba (guar gum)	†
D-myo-inositol	†
Taurine	†
Glucomannan (as *Amorphophallus konjac*) (root)	†
Alpha lipoic acid	†
D-pinitol††	†
L-leucine	†
Leucine ethyl ester HCl	†
Leucine methyl ester HCl	†
C_{12} Peption (Casein hydrolysate) (supplying 6% C_{12} peptide)	†
Taurine ketoisocaproic acid	†
Taurine alpha-ketoglutarate	†
Nitroxen™ (Amplified Nitric Oxide Accelerators) 712 mg	†
Glutamine peptides	†
L-glutamine	†
American ginseng extract (*Panax quinquefolius*) (Standardized for 5% ginsenosides)	†
N-acetyl cystaine	†
L-citrulline	†
N-acetyl tyrosine	†

*Percent Daily Values are based on a 2,000 calorie diet.
†Daily Value not established.

OTHER INGREDIENTS: PROTEIN BLEND (FEATURING NANO-DIFFUSETM WHEY

PROTEIN CONCENTRATE [PROVIDING DI-, TRI-, OLIGO-, AND POLYPEPTIDES AND NANODIFFUSED PROTEIN], HYPER-PURE WHEY PROTEIN ISOLATE [ION-EXCHANGED 97% PURITY], PARTIALLY HYDROLYZED WHEY), COCOA POWDER, NATURAL AND ARTIFICIAL FLAVORS, MALTODEXTRIN, SOY LECITHIN, ASPARTAME, SALT, SILICON DIOXIDE, ACESULFAME-POTASSIUM. CONTAINS MILK INGREDIENTS. PHENYLKETONURICS: CONTAINS PHENYLALANINE.

DIRECTIONS: Add 1 to 2 servings (1 to 2 scoops) of Nitro-Tech® Hardcore to 4 to 8 oz. of cold water or skim milk and mix. For maximum results, consume 2 servings of Nitro-Tech Hardcore 3 times daily for a minimum of 6 weeks.

Note: To maintain product freshness, store in a cool, dry place. This product is sold by weight. Some settling may occur. Shake container before use.

WARNING: Taking this product without adequate fluid may cause it to swell and block your throat or esophagus and may cause choking. Do not take this product if you have difficulty in swallowing. If you experience chest pain, vomiting, or difficulty in swallowing or breathing after taking this product, seek immediate medical attention.

CURRICULUM VITAE

Name: Marvin Arthur Heuer, MD

Address: 5100 Spectrum Way
Mississauga, Ontario L4W 5S2
Canada
Phone: (905) 678-4053
Facsimile: (905) 678-4055
Email: marvin.heuer@iovate.com

Medical License Number: ME 72101 (State of Florida), Arizona, Minnesota, Pennsylvania, New Jersey, California

Education: University of Minnesota Medical School
Minneapolis, Minnesota
MD Degree

Mankato State University
Mankato, Minnesota
BS Biology/Chemistry
With Honors

Graduate Training: St. John's Hospital
St. Paul, Minnesota
Internship

Certification: American Board of Family Practice 1976
Re-certified

Current Position: Iovate Health Sciences Inc
Chief Scientific Officer
5100 Spectrum Way
Mississauga, Ontario
Canada L4W 5S2

Chief Executive Officer
BioGalaxy, Inc.
3324 W University Ave. 151
Gainesville, FL 32607
Hydration Research, University of Florida
October 1998 - present

Prior Positions:

Chief Executive Officer
Clin Sci International, Inc. (CRO)
925 NW 56th Terrace, Suite B
Gainesville, Fl 32605
October 1998 - July 2003

Vice President
Florida Medical and Research Institute, PA
Gainesville, Fl and Ocala, Fl
September 1998 – May 2001

Vice President
IntegraMed America
Womens Health Fertility and Family Medicine
Located in Gainesville, FL
Corporate office in:
Purchase, New York
March 1997 – August 1998

Director of Family Practice and Clinical Research
Women's Medical and Diagnostic Center
Gainesville, Fl and Ocala, Fl
March 1997 – August 1998

Executive Consultant/Family Practice Physician
Medical Valley Biotechnology
Westview Clinic, PA
West St. Paul, Minnesota
November 1991 – March 1997

Vice President & Director Worldwide
Clinical Investigation, Therapeutic Unit
Research & Development Pharmaceuticals
SmithKline Beecham Pharmaceuticals
King of Prussia, Pennsylvania
April 1989 – December 1991

Vice President, Research & Development
Wallace Laboratories
Division of Carter- Wallace, Inc.
Cranbury, New Jersey
September 1987 – March 1989

Vice President, Clinical Research Worldwide

Vice President and Medical Director
Ayerst Laboratories
Division of American Home Products Corp.
New York, New York
July 1986 – September 1987

Director of Operations
R&D Clinical Investigations Worldwide
SmithKline and French laboratories
Philadelphia, Pennsylvania
1983- 1986

Group Director
R&D Clinical Investigations
SmithKline and French Laboratories
Philadelphia, Pennsylvania
1980-1983

Associate Director
R&D Clinical Investigations
SmithKline and French Laboratories
Philadelphia, Pennsylvania

Family Practice
General Medicine and Surgery and OB
Park Rapids, Minnesota
1974-1980

Teaching Appointments:

University of Florida
Adjunct Clinical Associate Professor
Department of Family Medicine
Gainesville, Fl
1998 – 2004

University of Minnesota
Clinical Associate Professor
Department of Family Medicine
Minneapolis, Minnesota
1992-2005

University of Iowa
Physician Assistant Programs
Assistant Professor/Preceptor
Iowa City, Iowa

1993-1999

University of Medicine and Dentistry of New Jersey
Clinical Associate Professor
Department of Family Medicine
Camden, New Jersey
1984-1992

Cooper Medical Center
Department of Family Medicine
Camden, New Jersey
1981-1992

University of Minnesota School of Nursing
Minneapolis, Minnesota
1977-1979

Patents and Applications

1. Improved ALA
   Alpha Lipoic acid based food supplement for increasing lean muscle mass and strength

2. NITRO-TECH
   Food supplement for increasing lean muscle mass and strength

3. ALA
   Food supplements and methods comprising lipoic acid and creatine (and methods for their use)

4. DIET-TECH
   Weight loss supplement

5. Dual Compartment Cap
   Dual compartment cap technology

6. ACETABOLAN
   Nutritional supplement for increased muscle size and strength for bodybuilders

7. Creatine & Glycogen
   Increasing creatine and glycogen concentration in muscle

8. PUMP-TECH, NITROXY-3, and 6-STAR NO

Nutritional composition for inducing muscle pump, enhancing muscle stimulus and recovery, increasing strength and increasing vascular response

9. PRO CHO
Compositions and methods for activating protein synthesis and deactivating catabolic processes in skeletal muscle

10. CREATINOL
Nutritional composition for promoting muscle performance and acting as hydrogen (H+) blocker

11. THERMOGAIN
Nutritional composition for increasing creatine uptake in skeletal muscle

12. LEAN BALANCE
Supplemental dietary composition for promoting weight loss

13. HYDROXYCUT – regular, carb control, caffeine free and natural
Nutritional composition which promotes weight loss, burn calories, increases thermogenesis, supports energy metabolism and or suppresses appetite

14. Performance and Recovery (GAKIC, FL)
Materials and methods for enhancing muscle performance and recovery from fatigue

15. Performance and Recovery (GAKIC, FL) CIPO, JPO, EPO
Supplementary dietary composition for enhancing muscle performance and or recovery from fatigue

16. GAKIC Improve
Supplementary dietary composition for enhancing muscle performance and or recovery from fatigue

17. AMINO ACID KIC
Supplemental dietary composition for turning on anabolic switches in muscle, stimulating and or optimizing protein synthesis, and or potently signaling muscle building and or growth

18. CREATINE HYDROXYCITRIC ACID
Creatine hydroxycitiric acid salts and methods for their production and use in animals

19. RED WINE
Compositions and methods for increasing muscle mass and strength, improving athletic performance, and reducing body fat mass leading to weight loss

20. 6-STAR PROTEIN
Supplemental dietary composition for supporting muscle growth, recovery and strength

21. 6-STAR CALORIE BURN
Compositions and methods for increasing metabolism, increasing energy and / or improving mental focus

22. THERMOSHRED
Compositions and methods for increasing thermogenesis and muscular definition

23. Melatonin GH
Compositions for increasing growth hormone, muscle development, fat loss, protein synthesis, IGF-1 release, and ameliorating exercise performance recovery

24. CEE-PRO
Supplemental dietary composition for increasing muscle size, strength, athletic performance and / or exercise capacity

25. ANTHOCYANINS
A combination consisting of, but not limited to, creatine, anthocyanins, and / or protein and / or carbohydrates and / or Cabernet Sauvinon grape skin compounds as a means of increasing muscle mass and strength, improving athletic performance / recovery, reducing fat mass, improving insulin secretion, and increasing protein synthesis

26. GLUT4
Nutritional composition for enhancing skeletal muscle mass, increasing muscle fatigue resistance and recovery, augmenting muscle glycogen deposition rate, preventing skeletal muscle protein catabolism, and / or reducing muscle soreness and inflammation

27. VIVABODY
Supplemental dietary composition for burning additional calories, providing sustained energy supporting weight loss and / or improving mental focus

28. CREATINE PYROGLUTAMATE

Supplemental dietary composition for increasing muscle strength, volume and / or size, improving concentration and / or mental focus, and / or improving cognition and / or attaining weight loss

29. EVERSLIM
Supplemental dietary composition for causing rapid weight loss, improving day time energy, promoting nighttime relaxations and sleep, controlling appetite and / or increasing metabolism

30. SMARTBURN
Supplemental dietary composition for causing rapid weight loss, controlling appetite, managing stress, supporting relaxation, combating fatigue and / or supporting mental well-being

31. HAMMERHEAD
Supplemental dietary composition including caffeine, taurine and ginseng

32. LEUCINE
Supplemental dietary composition including leucine

33. COROSOLIC ACID and HCA
Supplemental dietary composition including corosolic and HCA for weight loss

34. NOR CYCLE
Supplemental dietary composition to enhance muscle growth and enhance testosterone

35. CISSUS
Supplemental dietary composition for causing rapid weight loss

Honors and Awards:

Fellow of the American Academy of Family Physicians
1981-present

Diplomat American Board of Family Physicians
1976
Re-certified 1983
Re-certified 1994
Re-certified 2001

AMA Physicians Recognition Award

1976, 1979, 1982, 1983, 1984, 1987, 1990, 1992, 1993, 1994, 1997, 2000, 2003

University of Minnesota Residency Teaching Award
1977, 1979, 1980, 1993, 1994

Graduate Cum Laude with Honors
Mankato State University 1969

Marquis Who's Who in the US
1998, 2000, 2001, 2003, 2006

Marquis Who's Who in Science and Engineering
1992-1993, 1993-1994, 1995-1997, 2000

Marquis Who's Who of Emerging Leaders in America
1993-1994, 1994-1995, 2000, 2003, 2006

Societies:

American Medical Association
American Academy of Family Physicians
American Society of Clinical Pharmacology and Therapeutics
Society for Clinical Trials
Pharmaceutical Manufacturer's Association

Drug Information Association
American Diabetes Association
American Rheumatism Association
American College of Cardiology
American Heart Association
American College of Emergency Physicians
American College of Obstetrics & Gynecology
Pharmaceutical Physicians' Association
Aircraft Owners and Pilots Association
North American Menopause Society
Minnesota Street Rod Association

Administrative Services:

Medical Director
Fertility Services
Clear Passage Physical Therapy
Gainesville, Fl
1999 – present

Pharmacy Committee
Nature Coast Regional Hospital

Williston, FI
2001 – 2006

Clinical Associate Professor
University of Minnesota Medical School
Minneapolis, MN
1992 – 2005

Mankato State University
Biotechnology Advisory Council
Mankato, Minnesota
1986-present

Member, HealthSpan Integrated Provider Steering Committee
LifeSpan/Health One Provider Network
Minneapolis, Minnesota
1992-1997

Minnesota State Board of Medical Examiners
Physician Assistant Advisory Committee
St. Paul, Minnesota
1995-1997

Minnesota Medical Association
Drug Utilization Review Board
Minneapolis, Minnesota
1992-1997

Minnesota Academy of Family Physicians
Practice Research Steering Committee
PRN Monthly Newsletter
St. Paul, MN
1993-1995

Chair Education & Research Committee
United Hospital
St. Paul, Minnesota
1994

Chair Pharmacy and Therapeutics Committee
United Hospital
St. Paul, Minnesota
1995

Member Executive Committee

United Hospital
St. Paul, Minnesota
1994-1995

Member IPN Finance Committee
Allina IPN
Minneapolis, Minnesota
1993-1997

Medical Alley
Committee on Research
Minneapolis, MN
1994-1997

Clinical Associate Professor
University of Medicine and Dentistry
Camden, New Jersey
1983-1992

Mayo Medical School
Curriculum Advisor
Rochester, New York
1977-1983
1997 - present

Minnesota Academy of Family Physicians
Credentials Committee
1977-1996

Minnesota Academy of Family Physicians
Delegate
1977-1980, 1995

President - Elect
Upper Mississippi Medical Association
1978, 1980

St. Joseph's Hospital
Park Rapids, Minnesota
Chief of Staff 1979-1980
Chief of Obstetrics 1975-1980
Chief of Pediatrics 1976-1980
Joint Commission Committee 1977-1980

Community Services: Harn Museum Committee

University of Florida
Gainesville, FL
1998 – present

Chamber Orchestra Committee
Gainesville, FL
1998 – present

Gainesville Area Innovation Network
Gainesville, FL
2000 – present

Finance Committee
Incarnation Lutheran Church
St. Paul, Minnesota
1993-1997

Property Committee
Incarnation Lutheran Church
St. Paul, Minnesota
1992-1997

Youth Committee
Incarnation Lutheran Church
St. Paul, Minnesota
1992-1997

Trustee Committee
St. Matthews Lutheran Church
Morrestown, New Jersey
1983-1992

Pulpit Committee
St. Matthews Lutheran Church
Moorestown, New Jersey
1983-1985

Church Council
St. Matthews Lutheran Church
Morrestown, New Jersey
1981-1985

Youth Advisor
(Junior and Senior High)
St. Matthews Lutheran Church
Moorestown, New Jersey

1981-1985

Member, Advisory Board
Wadena Vo-Tech Institute
Medic and Paramedic Training
Park Rapids, Minnesota
1977-1980

City Health Officer
Park Rapids, Minnesota
1978-1980

City Health Officer
Nevis, Minnesota
1977-1980

Deputy Country Coroner
Hubbard County, Minnesota
1977-1980

Civil Air Patrol Advisor
Hubbard County, Minnesota
1977-1980

Parents Prenatal Classes Instructor
Hubbard County, Minnesota
1976-1980

Hubbard County Emergency Service Advisor
Hubbard County, Minnesota
1977-1980

Hubbard County Law Enforcement Committee
Hubbard County, Minnesota
1977-1980

Hobbies: Private pilot, scuba diving, skiing, racquetball, swimming, running, tennis, reading, encology, stained glass design, travel, computer programming, president or vice president of two small non-pharmaceutical companies, and family activities

Medical Licensure:

Florida	ME 72101
Arizona	13070

California	G-46189
Minnesota	021412-6
New Jersey	37976
Pennsylvania	MD 024331

Bibliography

Wurn, B., Wurn, L., King, R., Heuer, M., Roscow, A., Scharf, E., Shuster, J. Treating Female Infertility and Improving IVF Pregnancy With a Manual Physical Therapy Technique. Medscape 6/18/04

Heuer, M., Scharf. E., Cometa, A., A Review of Worldwide Experience with IV Immune Globulin Archives of Internal Medicine. Submitted for Publication (2001).

Scharf, E., Wurn, L., Heuer, M., Clinical Infertility Reversal Using Massage Therapy. Nature Submitted for Publication. (2001).

Heuer, M., Pietrusko, R., Morris, R., Scheffler, B., An Analysis of Worldwide Safety Experience with Auranofin, The Journal of Rheumatology 12:4 (1985), pp. 474-503

Heuer, M., Morris, R., SmithKline and French Worldwide Clinical Experience with Auranofin: A Review: Excerota Medica of Amsterdam, Excerpta Medica (1983)

Flagg, A., Stokes, A., Pietrusko, R. Heuer, M., Blodgett, R. Infrequent Occurrence of Thromocytopenia During Auranofin Internal Therapy (Accepted for Publication Archives of Medicine)

PRN Practice Research Network, Research Newsletter of MAFP Steering and Editorial Committee, 1993-Present

Heuer, M., Auranofin, Early Clinical Experience, Bioinorganic Chemistry of Gold Coordination Compounds, (1983) – Symposium Proceedings

Abstracts:

Wurn, L., Heuer, M., Massage Therapy for Infertility. Journal of American Medical Society. (2001)

Heuer, M.A. Intravenous Immunoglobulin Therapy :

Review of Clinical Applications, Efficacy and Safety. Clin Sci International, Inc. Gainesville, Fl. (2001)

Heuer, M., Wright, C. Trough Serum Levels of Estradiol, Estrone, and FSH Following Topical Application of ESTRASORB™ in a Phase III Clinical Trial. (2002)

D. Craig Wright, MD; Joan Brisker, BS (ASCP); Larry R. Muenz, PhD; Harold Boyenbaum, PhD; Marvin A. Heuer, MD Maria Gutierrez, MD. A Phase I Safety and Pharmacokinetic Study in Estradiol and Testosterone Deficient Postmenopausal Women of

MaxANDRASORB™ - A Topical Sustained-Release Testosterone Emulsion. (2001)

Heuer, M., MD; Wright, D.C., MD. A Phase I Pharmacokinetic Study of ESTRASORB™ Lotion, a Topical, Sustained-Release Estradiol Emulsion for Treatment Relief of Postmenopausal Vasomotor Symptoms. (2001)

Heuer, M., MD; Brisker, J.; Micellar Nanoparticles: A New Novel Topical Drug Delivery System for Systemic Delivery of Estradiol and Testosterone. (2001)

Wright, DC, MD; Brisker, J; Heuer, M: The Safety of ESTRASORB™, a New Topical Emulsion Technology for Systemic Delivery of Estradiol. (2001)

Brisker, J; Heuer, M, MD: Clinical Response as an Endpoint in Studies of Estrogen Replacement Therapy in Postmenopausal Women. (2001)

Pietrusko, R., Blodgett, R., Heuer, M., Proteinuria in Gold Treated Rheumatoid Arthritis. Submitted for Publication

Scheffler, B., Pietrusko, R., Heuer, M., Blodgett, R., Safety Profile Auranofin in the Elderly, Submitted for Publication

Scheffler, B., Hurley, J., Heuer, M., X-Ray Evaluation of Erosion Progression in RA: Double-Blind Study of

Auranofin vs. Placebo, Submitted for Publication

Pietrusko, R., Shirley, D., Heuer, M., Blodgett, R.: Blood Gold Levels During Chronic Auranofin Therapy. Submitted for Publication.

Schumacher, H, Heuer, M., Blodgett, R., Friedman, R. Effect of IM Gold and Other Disease Modifying Agents for Rheumatoid Arthritis After Treatment Failure on Auranofin. Submitted for Publication.

Presentations:

Lectures in Research and Medicine
General Topics (Arthritis, HRT, Osteoporosis, Hypertension, Erectile Dysfunction, OC, etc.)
Women's Health
Gainesville Florida
1997-present

Conducting Clinical Research
CME Allina Health Systems Course
Phillips Eye Institute
Minneapolis, Minnesota
1995 - 1997

Clinical Research From Start to Finish
CME Allina Health Systems Course
St. Paul, Minnesota
1994

Lectures in Research and Medicine
General Topics
Allina and Health East and Local Groups
St. Paul, Minnesota
1992-1997

Presentations Covering Research and Development and New Drug Approvals
SmithKline Beecham Pharmaceuticals
Philadelphia, Pennsylvania
1990-1992

Presentations Covering Development and Research Projects
Wallace Laboratories
Cranbury, New Jersey

1987-1989

Multiple Presentations Covering Development Projects
Ayerst Laboratories
New York, New York
1984-1987

Press Launches for New Ayerst Products (as required)
Ayerst Laboratories
New York, New York
1984-1987

DIA Labeling Workshop
How to Unify Adverse Reaction Listings on Product Labels
Philadelphia, Pennsylvania
January 1986

"The Medical Degree – A Golden Ticket!"
Cooper Medical School, University of Medicine and Dentistry of New Jersey
Camden, New Jersey
1985, 1986, 1987, 1988, 1992

Multiple Presentations Covering Development Projects
SmithKline and French Laboratories
Philadelphia, Pennsylvania

"The Development of New Pharmaceuticals"
University of Minnesota, Alumni Meeting
Minneapolis, Minnesota
1984

"Experience with Auranofin Therapy: A Review of Worldwide Date, European Congress of Rheumatology"
Moscow, Russia
1983

"Safety Profile of Auranofin in the Elderly"
Western Regional American Rheumatism Association
Tucson, Arizona
1983

"X-Ray Evaluation of Erosion Progression in RA:
Double-Blind Study of Auranofin vs. Placebo"
Philadelphia, Pennsylvania
1983

"Auranofin – Worldwide Safety Review"
Portugal
1983

"The Clinical and Safety Profile of Auranofin"
Singapore, Thailand, Malaysia
1983

"Auranofin, Early Clinical Experience"
Philadelphia, Pennsylvania
1982

FUNDED RESEARCH SUPPORT

1. SmithKline Beecham, 1981-1984
   Diagnostic Bioequivalence Studies and Reformation
   Monoacid Injectable Antibiotic Development Protocols
   Paxil Antidepressant Studies UK and US
   Obsessive Compulsive Studies US
   Relafen Full Development Plan and All Protocols
   RA and OA; Pain
   Pharmacokinetic Studies
   Ridawra – OA and RA Study Program
   Topical Use Eczema Program
   Tagamet – Ulcer Peptic and Gastric Studies
   Various Ophthalmologics Topical – Antibiotics, Steroids

2. Ayerst Laboratories, 1982-1986
   Altromid-S Protocols
   Inderal – Product Line Extension Hypertension
   Effexor – Antidepressant Study Program
   Lodine Development RA, OA Protocols
   PremPro Development Plan and Protocols
   Premarin Osteoporosis Program Development
   Prem Phase Development Plan and Protocols
   Various Oral Contraceptive Studies

3. Wallace Laboratories, 1987-1990
   Felbamate Development Program for Lennox Gasteau Syndrome,
   Seizures Organidin Reformulation Studies – cough / cold

4. SmithKline Beecham, 1990-1991
   Paxil, Carvedelol, Asthma, Arthritis

5. Scherrng Laboratories, 1981-1982
   Topical and Transdermal Delivery Systems

6. Upjohn Laboratories, 1981-1983
   Depression, Hypertension

7. Nautilus, Inc. 1982-1990
   Exercise Physiology and Osteoporosis

8. Ayerst Laboratories 1982
   Premarin, GNRH

9. FL Dept. of Health & Rehabilitative Services I, 1983

10. FL Dept. of Health & Rehabilitative Services II, 1983-1984

11. Bruner Foundation, 1983-1985

12. Schering Laboratories, 1983-1984

13. Ciba-Geigy, 1983-1984
    Opthalmologics, Antihypertensives

14. Ayerst Laboratories, 1985

15. Wyeth Laboratories, 1985

16. Nuclear Data, 1985-1986

17. Lederle Laboratories, 1986

18. Florida Department of Health and Rehabilitative Services III, 1986

19. Abbott Laboratories, 1986

20. Ayerst Laboratories, 1987

21. NIH (Co-Investigator with Dan Martin, Ph.D.) Walking and Bone Mass, 1988-1990

22. Ayerst Estrogen, Exercise and Lipid Study, 1988-1990

23. Reid-Rowell Estratab and Estratest and Effects on Lipids and Bone Mass, 1988-1990

24. Bartor Estrapel and Effects of Estradiol Production Levels, 1989

25. Columbia Laboratories, Inc. Vaginal Moisturizing Gel Study, 1989

26. Organon, Inc. Desogestrel O.C. CTR-04 Study, 1990

27. Health & Sciences Research, Inc. Noven Patch Study , 1990

28. 3M/Bio –Pharm Estradiol Patch Study, 1990

29. Wyeth-Ayerst Laboratories: Trigonitis, 1992

30. Miles, Inc.: Clotrimazole 2% Vaginal Cream, 1993

Research Experience

Hormone Replacement Therapy

Mead Johnson Laboratories: Evaluation of the Effect of the 0.5 mg Estrace Compared to Placebo on Biochemical Markers of Bone Resorption in Postmenopausal Women, 1994

Kabi Pharmacia: Comparison of a Continuous Low Dose of Estradiol Released From a Vaginal Ring vs. Conjugated Equine Estrogen in a Vaginal Cream in the Treatment of Postmenopausal Women with Signs and Symptoms of Urogenital Atrophy, 1992.

Zeneca Pharmaceuticals Group: Comparison of 3.6 mg ZOLADEX therapy with or without hormone replacement therapy for the treatment of endometriosis, 1992.

Novo Nordisk Pharmaceuticals, Inc.: Evaluation of Estrofem® 0.25, 0.5, 1.0, and 2.0 mg on relief of vasomotor and other symptoms of the menopause, 1993.

Solvay Pharmaceuticals, Inc.: Investigation of Three Doses of Esterifield Estrogens (Estratab®) on Bone Mineral Density and Parameters of Bone Metabolism in Postmenopausal Women, 1992.

Solvay Pharmaceuticals, Inc.: Study of the Effects of Estratest H.S.®, Estratest®, and Premarin® in Surgically Menopausal women, 1992.
Solvay Pharmaceuticals, Inc.: Study of Estrafied Estrogens Plus Methyltesterone (Estratest®) and Esterified Estrogens (Estratab® 1.25

mg) in Surgically Postmenopausal Women: Symptoms, Psychometric Assessments, Serum and Saliva Hormone Levels, 1993.

ClinTrials Research Inc./TheraTech, Inc.: Comparison of Two Doses of an Estradiol Matrix Transdermal Delivery System (EMTDS) with Placebo Matrix Transdermal Delivery System I the Treatment of women with Postmenopausal Symptom, 1994.

Novo Nordisk Pharmaceuticals, Inc. (Protocol VAG/PD/9/USA) "A Randomized, Double-Blind, Placebo-Controlled, Parallel Group Multicenter Study Comparing the Efficacy and safety of Vagifem 10 μg and 25 μg doses in Treatment of Estrogen Deficiency Derived Atrophic Vaginitis."

Ostex International, Inc. (Protocol OST-C2) :A Study of the Use of Osteomark in the Quantitation of Cross-Linked N-telopeptides of a Type I Collagen as an Aid in Monitoring the Effect of Therapies Used for the Prevention and Management of Bone Loss in Postmenopausal Women"

ClinTrials Research, Inc. TheraTech, Inc. (Protocol E94001A) "An Open-Label, Multicenter Extension of Protocol No. E94001 to Describe the Use of Two Doses of an Estradiol Matrix Transdermal Delivery System (EMTDS) in the Treatment of Women with Postmenopausal Symptoms."

Novo Nordisk Pharmaceuticals, Inc. (Protocol KLIM/PD/7/USA) "A Double-Blind, Randomized, Parallel Group, Multicenter, Dose Finding Study Comparing the Efficacy and Safety of 1 mg 17β-Estradiol in Combination With Low Doses of Norethindrone Acetate with that of 1 mg 17β-Estradiol Alone on the Endometrium in Postmenopausal Women."

Rhone-Poulace Rorer (Protocol RPR 106522-303) "A Randomized, Double-Blind, Multicenter, Placebo-Controlled, Menopausal Symptom study of Three Doses of RPR Estradiol Norethisterone Acetate (NETA) Patches in a Sequential Wear Hormone Replacement Therapy (HRT) Regimen."

Sterling Winthrop Pharmaceuticals (Protocol SR41319B-004) "A Phase III Study of Intermittent Cyclical Tiludronate in the Treatment of Established Post-Menopausal Osteoporosis."

The Upjohn Company (Protocol M5410/0336) "Evaluation of Endometrial Histology and Bone Mineral Density (BMD) in Postmenopausal Women Receiving (OGEN/PROVERA) Hormone Replacement Therapy (HRT)."

Eli Lilly & Company (Protocol H3S-MC-GGHG) "Comparison of Raloxifene HCl, Estrogen and Placebo on the Uterus in Healthy Postmenopausal

Women."

R.W. Johnson PRI (Protocol ESTNRG-CHRT-102) "A Multicenter, Randomized, Double-Blind, Parallel Group, Dose-Ranging Study to Evaluate the Safety of a CYCLOPHASIC Hormone Replacement Therapy Regimen of Estradiol and Norgestimate and its Effects on Endometrial Histology, Vaginal Bleeding and Metabolic Parameters in Postmenopausal Women."

R.W. Johnson (Protocol ESTNRG-CHRT-104) "A Multicenter, Double-Blind, Randomized Parallel Group, Placebo Controlled Study to Evaluate the Safety and Efficacy of Oral 17β-Estradiol for the Treatment of

Vasomotor Symptoms and Genital Atrophy in Postmenopausal Women."

Eli Lilly & Company (Protocol H3S-MC-GGHD) "Comparison of Raloxifene HCL, Continuous Combined Hormone Replacement Therapy and Placebo in Early Postmenopausal Women: Once a Week Estradiol-Levonorgestrel Combination Transdermal System (TDS).

Novo Nordisk Pharmaceuticals, Inc. (Protocol KLIM/USA/1/USA) "Bleeding Profile with Continuous0Combined Hormone Replacement Therapy: A Randomized, Double-Blind, Multicenter, Comparative Trial of 1 mg 17B-Estradiol in Combination with 0.25 mg Or 0.5 mg Norethindrone Acetate and Prempro®."

Procter & Gamble Pharmaceuticals (Protocol 1996023) A Randomized, Double-Blind, Placebo-Controlled 24 Month, Dose Ranging , Multicenter Study Protocol Comparing EMTDS to Placebo in the Prevention of Bone Loss in Hysterectomized Postmenopausal Women."

Ethical Pharmaceuticals (UK) Ltd. (Protocol EPCOUS02) "A Clinical Evaluation of the Effects of Estradiol TD and Combi TD, Used Continuously, on Estradiol-Induced Endometrial Hyperplasia."

Berlex Laboratories, Inc. (Protocol 96097) "A Multicenter, Double-Blind, Randomized Comparison of Continuous Oral Estradiol-Drospirnone Combinations and Continuous Oral Estradiol, Examining the Effects on the Endometrium, Symptom, and Bleeding Patterns in Postmenopausal Women."

RW Johnson Pharmaceuticals Research Institute (Protocol ESTRNG-CHRT-106) "A Multicenter, Randomized, Double-Blind Exploratory Study Investigating the Pharmacodynamic Profile of Two Different Hormone Replacement Therapy Regimens: Conjugated Estrogens plus Medroxyprogesterone Acetate vs. Micronized Estradiol plus Cyclophasic

Addition of Norgestimate (Cyclophasic HRT) vs. Placebo in Postmenopausal Women."

Procter & Gamble Pharmaceuticals / TheraTech (Protocol 1998049) "A 12-week, Randomized, Parallel Group, Multicenter, Wear Study to Assess skin Tolerance With a 40-Week safety Extension Period Comparing Three Continuous Dose Regimens (0.1, 0.2, and 0.4 mg/day NETA Combined with 0.05 mg/day Estradiol) Under Condition of Routine Clinical Use."

Wyeth-Ayerst Research (Protocol 0802D1-324-US) "A Randomized, Double-Blind, Placebo and Active-Controlled, Parallel, Multicenter Study to Assess the Safety and Efficacy of 3 ½ Day Combinations of 17β-Estradiol/Norethindrone Acetate Transdermal Delivery Systems for Relief of Menopausal Vasomotor Symptoms and Reduction of Endometrial Hyperplasia."

Oral Contraceptives

Organon, Inc./Pharmaco LSR (Protocol 086-001) "An Open Label, Multicenter, Non-Comparative Safety and Efficacy Study of the Desogestrel Containing Oral Contraceptive CTR 25."

Organon, Inc./Pharmaco LSR (Protocol 092-001) "An Open-Label, Randomized, Parallel, Comparative, Multicenter, Safety and Efficacy Study of Triphasic Combination Oral Contraceptives, CTR 99 and CTR 77, versus Ortho-Novum 777).

Organon, Inc./Quintiles, Inc. (Protocol 069-001) "An Open-Label Noncomparative Efficacy and Safety Study of Implanon, a one-Rod Contraceptive Implant Containing 3-Ketodesogestrel in Healthy Female Volunteers, With subsets For Pharmacokinetic Measurements, Ophthalmological Assessments, Carbohydrate Metabolism, Lipid Metabolism and Endometrial Morphology."

Ortho-McNeil Pharmaceutical (Protocol CAPSS022) "A Comparison of Two Oral Contraceptives: Oral Tri-Cyclen® vs. Loestrin® Fe 1/20."

RW Johnson Pharmaceutical Research Institute (Protocol NRGEEP-CONT-004) "An Open-Label Study to Evaluate Contraceptive Efficacy ad Safety of the Transdermal Contraceptive System of 17-Deacetylnorgestimate and Ethinyl Estradiol with the Oral Contraceptive Triphasil."

Organon, Inc. (Protocol 147-001) "A Randomized, Open-Label, Comparative, Multicenter Trial to Evaluate Contraceptive Efficacy, Cycle Control, Safety and Acceptability of a Monophasic COC Containing 200μg EE, Compared to a COC Containing 100μg Levonorgestrel and 20μg EE."

Osteoporosis

Procter & Gamble Pharmaceuticals/G.H. Besselaar Associates (Protocol RPE 002494) "A Randomized, Double-Blind, Placebo-Controlled, Multicenter, Parallel Group Study to Compare the Efficacy and Safety of Risedronate (NE-58095) plus Estrogen versus Estrogen Only in the Prevention of Bone Mineral Mass and No Vertebral Fractures."

Sterling Winthrop Pharmaceuticals (Protocol SR 41319B-005) "A Phase III Study of Intermittent Cyclical Tiludronate in the Treatment of Post-Menopausal Women with Low Bone Mineral Mass and No Vertebral Fractures."

Ostex International, Inc. (Protocol OST-C2) :A Study of the Use of Osteomark in the Quantitation of Cross-Linked N-telopeptides of a Type I Collagen as an Aid in Monitoring the Effect of Therapies Used for the Prevention and Management of Bone Loss in Postmenopausal Women"

Mead Johnson Laboratories: Evaluation of the Effect of the 0.5 mg Estrace Compared to Placebo on Biochemical Markers of Bone Resorption in Postmenopausal Women, 1994

Solvay Pharmaceuticals, Inc.: Investigation of Three Doses of Esterifield Estrogens (Estratab®) on Bone Mineral Density and Parameters of Bone Metabolism in Postmenopausal Women, 1992.

Sterling Winthrop Pharmaceuticals (Protocol SR41319B-004) "A Phase III Study of Intermittent Cyclical Tiludronate in the Treatment of Established Post-Menopausal Osteoporosis."

Organon, Inc. (Protocol 010-006) "A Dose-Finding Efficacy & Safety Study of Tibolone (Org OD 14) for Prevention of Osteoporosis in Postmenopausal Women."

The Upjohn Company (Protocol M5410/0336) "Evaluation of Endometrial Histology and Bone Mineral Density (BMD) in Postmenopausal Women Receiving (OGEN/PROVERA) Hormone Replacement Therapy (HRT)."

Procter & Gamble Pharmaceuticals/G.H. Besselaar Associates (protocol

RVN008993) "A Randomized, Double-Blind, Placebo-Controlled, Multicenter, Parallel Group Study to Determine the Efficacy and Safety of Risedronate (NE-58095) in the Treatment of Postmenopausal Women with Established Osteoporosis-Related Vertebral Deformities."

Procter & Gamble Pharmaceuticals / Quintiles Inc. (Protocol RHN009193) "A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel Group study to Determine the Efficacy and Safety of Risedronate in the Treatment of Osteoposoris in Elderly Women."

Novo Nordisk Pharmaceuticals, Inc. (Protocol LEV/PD/15/USA) "A Double-Blind, Randomized Placebo Controlled Trial of Three Doses of Levomeloxifene and Prempro® for the Prevention of Postmenopausal Osteoporosis."

Novo Nordisk Pharmaceuticals, Inc. (Protocol LEV/PD/16/USA) "A Double Blind, Randomized, Multicenter, Placebo-Controlled Trial of 1.25 and 2.5 mg of Levormeloxifene for the Treatment of Postmenopausal Osteoporosis."

Novo Nordisk Pharmaceuticals, Inc. (Protocol LEV/PD/17/USA) "A Double-Blind, Placebo Controlled Trial To Study the Safety and Efficacy of 2.5, 10, and 40 mg of Levormeloxifene for the Prevention of Postmenopausal Bone Loss."

Boehringer Manheim Pharmaceuticals Corporation (Protocol MF4380) "Double-Blind, Placebo-Controlled, Randomized, Multicenter Study on the Efficacy and Safety of Ibandronate (BM 21.0955) During Three Years Treatment in Patients with Postmenopausal Osteoporosis Using an Intermittent (every 3 months) I.V. Injection Regimen of 1 mg."

Roche Pharmaceuticals (Protocol MF4492) "Double-Blind, Placebo-Controlled, Randomized, Multicenter Study on the Efficacy and Safety of Ibandronate During an Extended Two Year Partial Crossover Study of Patients Enrolled in MF4380 Using an Intermittent I.V. Injection Regimen of 0.5 mg and 1 mg Every 3 Months."

Eli Lilly & Company (Protocol H3S-MC-GGGK) "Comparison of Raloxifene HCl and Placebo in the Treatment of Postmenopausal Women with Osteoporosis."

Eli Lilly & Company (Protocol H3S-MC-GGHF) "Raloxifene HCl Versus Placebo Versus Hormone Replacement Therapy: Histomorphologic Effects in Bone Loss."

Pfizer, Inc. (Protocol 174-106) "A Randomized, Double-Blind, Placebo

Controlled Study of the Effects of Droloxifene 40 mg/d, 60 mg/d, and 80 mg/d on BMD in Osteopenic, Postmenopausal Women."

Procter & Gamble Pharmaceuticals (Protocol 1996023) A Randomized, Double-Blind, Placebo-Controlled 24 Month, Dose Ranging , Multicenter Study Protocol Comparing EMTDS to Placebo in the Prevention of Bone Loss in Hysterectomized Postmenopausal Women."

Pfizer, Inc. (Protocol 174-113) "A Study of the Safety and Efficacy of Droloxifene for Preventing Bone Loss in Normal, Early Postmenopausal Women."

Pfizer, Inc. (Protocol A2181003-5045) "A Study of the Safety and Efficacy of Lasofoxifene for the Prevention of Bone Loss and for Lipid Lowering in Postmenopausal Women at Risk for Osteoporosis."

Overactive Bladder and Urinary Incontinence

Eli Lilly & Company (Protocol H3S-MC-SAAL) "Duloxetine Versus Oxybutnin in Patients with Urge Incontinence: A Multiple-Dose Study for Efficacy and Safety."

Pharmacia & Upjohn Pharmaceuticals (Protocol 97 OATA 039) "Dose Escalation Study with Tolterodine in Patients with Overactive Bladder. A Single-Blind Study in Patients with Symptoms of Overactive Bladder Including Urinary Urgency and Frequency With or Without Urge Incontinence."

Pharmacia & Upjohn Pharmaceuticals (Protocol 98-TOCR-007) "Long-Term Safety and Efficacy of Tolterodine Prolonged Release Capsules. An Open-Label, Uncontrolled, Multinational Study in Patients with Symptoms of Overactive Bladder."

Pharmacia & Upjohn Pharmaceuticals (Protocol 98-TOCR-007B) "Long-Term Safety and Efficacy of Tolterodine Prolonged Release Capsules. An Open-Label, Uncontrolled, Multinational Study in Patients with Symptoms of Overactive Bladder."

Candidiasis

Bayer Corporation (Protocol S95-003) "A Multicenter, Prospective, Randomized, single-Blind, Parallel-Group Comparison of the Clotrimazole 1-Day (One 500 mg Vaginal Insert) and the Clotrimazole 3-Day Regimens (One 200 mg Vaginal Insert Daily for 3 Days) with Clotrimazole 7-Day

Regimen (One 100 mg Vaginal Insert Daily for 7 Days) for the Treatment of Vulvovaginal Candidiasis."

Advance Care Products, Ortho Pharmaceutical Corporaqtion (Protocol 94-007P) "Phase III Study Comparing Micanzole Nitrate (4%) Vaginal Cream and Mixanozole Nitrate (2.8%) Vaginal Cream to MONISTAT® 7 (2%) Vaginal Cream in the Treatment of Vulvovaginal Candidiasis."

Urinary Tract Infection

Bayer (Protocol 100398) "Prospective, randomized, double-blind, multicenter, comparative trial to evaluate the efficacy and safety of ciprofloxacin once daily extended release 500mg tablets QD for 3 days *versus* conventional ciprofloxacin 250mg tablets BID for 3 days in the treatment of patients with uncomplicated urinary tract infections".

Acute Exacerbation of Chronic Bronchitis

Abbott Laboratories, Inc. (Protocol M97-766) "Comparative Study of the Efficacy of Clarithromycin and Azithromycin for the Treatment of Patients with Acute Exacerbation of Chronic Bronchitis."

Community Acquired Pneumonia

Abbott Laboratories, Inc. (Protocol M98-939) "Comparison of the Safety of Clarithromycin IR (250 mg) BID to Levofloxacin (500 mg OD) for the Treatment of Community-Acquired Pneumonia."

TAP Holdings (Protocol CEF-97-002) "A Comparative Study on the Safety and Efficacy of CefditorenPivoxil and Cefpodoxime Proxetil in the Treatment of Community-Acquired Pneumonia."

Endometriosis

IBAH / Searle Research and Development (Protocol N65-97-02-001) "Clinical Protocol for a Dosing Optimazation Study of Syneral® for Endometriosis: Safety and Efficacy of a Single 400μG Daily Dose for 6 Months and a Step-Down Dose from 200μG BID for 2 Months to 200μG

Daily for 4 Months. A Double-Blind, Placebo-Controlled, Randomized Comparison to the Currently Recommended Regimen of 200μG BID Daily

for 6 Months, IND # 18,138."

Hypertension

GD Searle & Company (Protocol IE3-98-02-01) "A Double-Blind, Placebo-Controlled, Randomized Study to Evaluate the safety and Efficacy of Ranging Doses of Eplernone Relative to Placebo, Hydrochlorothiazide and Daily Dose Combinations of Eplernone and Hydrochlorothiazide For the Treatment of Mild to Moderate Hypertension."

ALLHAT National Trial on Hypertension Agents and Heart Disease. 5-year NIH trial

Arthritis

Merck Industries (Protocol 088-001) "A Double-Blind, Randomized, Stratified, Parallel-Group Study to Assess the Incidence of PUB's During Chronic Treatment with MK-0966 or Naproxen in Patients with Rheumatoid Arthritis."

GD Searle & Company (Protocol N49-98-02-102) "Clinical Protocol for a Multicenter, Double-Blind, Parallel Group Study Comparing the Incidence of Clinically Significant Upper Gastorintestinal Adverse Events Associated with SC-58635 400 mg BID to That of Diclofenac 75 mg BID in Patients With Osteoarthritis or Rheumatoid Arthritis, IND # 48,395."

Diabetes

Insmed Pharmaceuticals (Protocol INS1-DM-28) "A Randomized, Multicenter, Double-Blind, Parallel-Group Clinical Study to Compare the Effects of INS1 (D-Chiro-Inositol) Versus Placebo as Initial Oral Therapy in Subjects with Type 2 Diabetes Mellitus Who Fail to Achieve Adequate Glycemic Control with Diet and Exercise Alone."

Bristol-Myers Squibb US Pharmaceuticals (Protocol CV 138-002) "Comparative Outcomes Study of Metformin Invention Versus Conventional Approach: The Cosmic Approach Study."

Lipid Lowering

Pharmacia Corporation (Protocol NB4-00-02-009) "Clinical Protocol for a Randomized, Double-blind, Placebo-controlled Study of SD-5613 as

Monotherapy in Patients with Primary Hypercholesterolemia (Monotherapy Assessment of Reducing Cholesterol [MONARCH]), IND #58,482."

Sinusitis

Abbott Laboratories (Protocol M00-225) "Comparative Study of the Safety and Efficacy of ABT-773 150 mg QD vs. 150 mg BID for the Treatment of Acute Bacterial Sinusitis."

Migraine

Wyeth-Ayerst Inderol LA in Chronic Severe Migraine. Inderol LA 160mg vs. Inderol 40mg TID vs. Calcium Channel Blocker.

Glaxo Welcome. Imitrex Injection in the Treatment of Acute Migraine and Cluster Migraine.

Glaxo Welcome. Imitrex Injection vs. Imitrex Tablets in Chronic Severe Migraine.